

The Commonwealth of Massachusetts Executive Office of Health and Human Services

Department of Public Health

250 Washington Street, Boston, MA 02108-4619

Governor KARYN E. POLITO

Lieutenant Governor

MARYLOU SUDDERS Secretary

MONICA BHAREL, MD, MPH Commissioner

> Tel: 617-624-6000 www.mass.gov/dph

June 19, 2015

Alternative Therapies Group, Inc. Mr. Christopher Edwards 24 R. Pleasant St. Unit 2 Newburyport, MA 01950

Re:

Request for a Waiver

Dear Mr. Edwards:

Alternative Therapies Group ("ATG") has submitted a written request for a waiver. pursuant to 105 CMR 725.700, from the requirements set forth in 105 CMR 725.105(C)(2), 105 CMR 725.105(E)(2)(g), and 105(E)(3)(i). In that waiver request, you have represented that the two Massachusetts laboratories conducting testing on marijuana products are currently unable to "provide the full array of required finished product testing" and "[e]ven if both laboratories were to test the same samples, the combined tests that they are able to offer at this time still do not cover the full spectrum of required tests."

I find that compliance would cause undue hardship to ATG and patients, that ATG will institute compensating features acceptable to the Department of Public Health (the "Department") and that with those compensating features, non-compliance does not jeopardize the health or safety of any patient or the public. ATG's request for a waiver is granted only for finished plant material, and only from 105 CMR 725.105(C)(2)(a) as it applies to heavy metals and pesticides, and 105 CMR 725.105(E)(2)(g), and with the following conditions.

1. For three (3) months from the date of this letter (the "Waiver Term") or until such time that ATG has demonstrated to the Department's satisfaction that it can fully comply with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Marijuana Dispensaries and Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused

Products for Massachusetts Registered Medical Marijuana Dispensaries (collectively, the "Protocols"), whichever occurs earlier, it may only dispense a maximum of 4.23 ounces of finished plant material to any qualifying patient or caregiver for their sixty-day supply and must supply each qualifying patient or caregiver with instructions that a maximum of 2 grams of finished plant material may be consumed per day;

- 2. During the Waiver Term, ATG shall continue to conduct testing in compliance with the Protocols for finished plant material for all substances listed in 105 CMR 725.105(C)(2)(a), including heavy metals and pesticides, and submit the results to the Department;
- 3. During the Waiver Term, ATG shall take all necessary steps to ensure that the presence of heavy metals in finished plant material is as minimal as possible, but shall not be required to meet the levels specified in Exhibit 4 of Section 7 of the *Protocol for Sampling and Analysis of Finished Medical Marijuana and Marijuana-Infused Product for Massachusetts Registered Marijuana Dispensaries*;
- 4. Consistent with ATG's representation in its request that it does not use the plant-growth regulators and pesticides identified in the Protocol, ATG shall not use any of the plant-growth regulators and pesticides identified in the Protocol during the Waiver Term;
- 5. During the Waiver Term, ATG shall be subject to increased inspections to ensure compliance with the conditions of this Waiver, including requests for additional testing and information regarding the testing capabilities of any independent laboratory selected for testing by ATG;
- 6. ATG must maintain records available for inspection by the Department that it only dispenses a maximum of 4.23 ounces of finished plant material to any qualifying patient or caregiver for their sixty-day supply and that each qualifying patient has received the instructions that a maximum of 2 grams of finished plant material may be consumed per day;
- 7. Labels for all marijuana finished plant material produced during the Waiver Term shall disclose that product may not meet the established standards for heavy metals and pesticides:
 - "WARNING: This product may not meet the established standards for heavy metals and pesticides."

8. The Department reserves the right to revoke or modify this waiver at any time should it determine that ATG, or any of its dispensary agents, fail to comply with the terms and conditions of the waiver, or if the Department finds that the waiver no longer serves the interests of the public health or safety.

The Department anticipates that ATG will work expeditiously to resolve the issues that have led to the request for this Waiver. If, however, ATG determines it cannot do so within the Waiver Term, a request for any additional Waiver must be received by the Department 14 days prior to the expiration of the current Waiver. Please contact RMDcompliance@state.ma.us with any questions regarding this Waiver.

Sincerely,

Monica Bharel, MD, MPH

Commissioner

Massachusetts Department of Public Health